

DOCKET NO.: VTN5023  
Application No.: 10/699,417

PATENT

## REMARKS/ARGUMENTS

A petition for a three month extension of time is submitted herewith.

Examiner has rejected claims 1-11, 13 and 15-17 as indefinite under 35 U.S.C. 112 because of the presence of phrases beginning with "preferably" and "more preferably" in claim 1. These phrases have been deleted. Withdrawal of the rejection is respectfully requested.

Examiner has rejected claims 1-4, 10, 11, 13 and 15-17 as unpatentable over Hoffman et al. (US 5,607,518) in view of Bawa et al (US 6,071,439) and Romack (US 6,200,393) taken in view of one or more of Nicolson et al (US 5,760,100) or the Spinelli et al. patents (US 5,371,147, 5019,628 or 4,810,756).

Hoffman et al. and Bawa et al. disclose processes for removing impurities from a contact lens. In both processes the super critical fluid is "applied to a contact lens affixed to a mold subsequent to the polymerization step". See Hoffman et al, abstract and Bawa et al. Col. 3, lines 57-63. Use of supercritical fluid extraction for purification of anything other than a polymeric article is not disclosed or suggested.

Romack et al. discloses a carbon dioxide cleaning and separation system. The systems are disclosed to be useful for separating contaminants from a cleaner (col. 1, lines 46-50) and recovering oil, such as vegetable oil, for reuse (Col. 1, lines 51-53). Romack et al. neither discloses nor suggests that any silicone compounds, let alone the silicone compounds recited in claim 1 could be purified via the carbon dioxide cleaning systems disclosed therein.

Nicolson et al. and the Spinelli et al. patents disclose various polymerizable materials which may be used to make contact lenses. Methods for purifying the polymerizable materials used to make the contact lenses are neither disclosed nor suggested.

Unlike the references cited, the present invention relates to the purification of certain recited free radical reactive silicone containing compounds.

These compounds must be free of undesirable impurities to insure that suitable medical devices, and particularly ophthalmic devices may be produced. Typically the silicone containing compounds also include reactive groups which are polymerizable via free radical polymerization. These free radical reactive groups can complicate

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traditional purification techniques, such as distillation, requiring control of the distillation temperature to avoid gellation. In the case of high molecular weight silicone-containing compounds, e.g., molecular weights great than about 1000 Dalton, distillation is not possible due to the extremely high boiling points of the silicone containing compounds. Page 1, lines 10-19 of the present specification.

None of Nicolson et al. or the Spinelli et al. patents disclose or suggest that the reactive components disclosed therein should be purified, let alone processes for purifying reactive compounds, such as those disclosed in the present application.

Accordingly, Applicants submit that the present invention is not obvious in view of the combination of Hoffman et al. and Bawa et al. in view of Romack et al., further in view of Nicolson et al. or the Spinelli et al. patents. Assuming a *prima facia* case had been made out, Applicants submit that the use of supercritical fluid extraction to purify the monomers recited in claim 1 does more than yield a predictable result. The examples of the present invention clearly show that very substantial improvements in purity may be achieved.

"These conditions led to a greatly improved purity of the SiMAA2 with significant decreases in the impurity by-products. Removal of the high molecular weight species is particularly efficient, with their concentrations being reduced by an order of magnitude." Example 6, page 19, lines 8-10. This is particularly significant as convention methods, such as distillation can lead to unwanted results, such as gellation.

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Applicants respectfully submit that the amendments and arguments have traversed Examiner's rejections and objections. Withdrawal of the rejections, and allowance of the claims as amended is requested.

Respectfully submitted,

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